

# PATENT COOPERATION TREATY

REC'D 17 JUN 2005

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PCT

From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/GB2005/000165

International filing date (day/month/year)  
21.01.2005

Priority date (day/month/year)  
22.01.2004

International Patent Classification (IPC) or both national classification and IPC  
A61F2/44, A61F2/30

Applicant  
DEPUY INTERNATIONAL LIMITED

### 1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b/s(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523655 epmu d  
Fax: +49 89 2399 - 4465

Authorized Officer

Buchmann, G

Telephone No. +49 89 2399-2288



**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2005/000165

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
- 3: ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2005/000165

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 26-30

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 26-30
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
  - the written form ☐ has not been furnished
  - ☐ does not comply with the standard
  - the computer readable form ☐ has not been furnished
  - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2005/000165

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

|                               |             |                 |
|-------------------------------|-------------|-----------------|
| Novelty (N)                   | Yes: Claims | 4,5,22,23,31    |
|                               | No: Claims  | 1-3,6-21,24,25, |
| Inventive step (IS)           | Yes: Claims | 22,23,31        |
|                               | No: Claims  | 1-21,24,25,     |
| Industrial applicability (IA) | Yes: Claims | 1-25,31         |
|                               | No: Claims  |                 |

**2. Citations and explanations**

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item III.**

Claims 26-30 of the present application define methods for use in an intervertebral fusion surgical procedure, comprising the step of introducing a cage into the intervertebral space. This step represents a method for surgical treatment of the human body in the sense of Rule 67.1 (iv) PCT. Therefore, no examination is carried out for these claims according to Art. 34 (4)(a)(I) PCT.

**Re Item V.**

- 1 Reference is made to the following documents:  
D1 : WO 00/45751 A (SYNTHES AG CHUR; SYNTHES ; MESSERLI, DOMINIQUE,  
D; PAUL, DAVID, C) 10 August 2000 (2000-08-10)  
D2 : EP 0 966 930 A (BIOMET MERCK LIMITED) 29 December 1999 (1999-12-29)

**2 INDEPENDENT CLAIM 1**

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.  
Document D1 discloses (see page 5 and 6, and fig. 1):  
An end cap (10) for an intervertebral cage (22), comprising
  - an annular body (12, 14),
  - a projection (12, 16), engaging with an edge of the cage, and
  - a formation 34, 36) which is suitable for mating with an end plate.

The definition in the present claim 1, that the outer surface of the body is flush with the surface of the end plate, is not a feature of the end cap itself (see below, clarity).

The subject-matter of claim 1 is therefore already known from document D1.

**3 INDEPENDENT CLAIM 13**

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 13 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (see page 8, paragraph 4, and fig. 8):

An end cap (610) for an intervertebral cage (22), comprising

- an annular body (14),
- a projection (16), engaging with an edge of the cage, and
- flexible members (40) extending from the underside of the body, each flexible member having a grip for engaging with an inner surface of the cage.

The subject-matter of claim 13 is therefore already known from document D1.

**4 INDEPENDENT CLAIM 24**

- 4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 24 is not new in the sense of Article 33(2) PCT.

Document D2 discloses (see paragraphs (0037)-(0039)):

A method for use in an intervertebral fusion surgical procedure, comprising the steps of

- push fitting a first annular end cap into the end of a cage,
- packing the interior of the cage with a bone fusion enhancing material via an opening of the end cap.

The subject-matter of claim 24 is therefore already known from document D3.

**5 DEPENDENT CLAIMS 2-12, 14-21, 25**

Dependent claims 2-12, 14-21, 25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

See the documents cited in the international search report and the corresponding passages.

**6 INDEPENDENT CLAIMS 22 AND 31**

- 6.1 Document D1, which is considered to represent the most relevant state of the art, discloses (the references in parentheses applying to this document):

A kit for assembling into an intervertebral fusion device, comprising:

- An end cap (610) for an intervertebral cage (22), comprising
  - an annular body (14),
  - a projection (16), engaging with an edge of the cage, and
  - flexible members (40) extending from the underside of the body, each flexible member having a grip for engaging with an inner surface of the cage.

From this, the subject-matter of independent claims 22 and 31 differs in that:  
An end plate is provided having a formation mating with a formation on the end cap, such when assembled, the surfaces of the end cap and the end plate are flush.

The subject-matter of claims 22 and 31 is therefore novel (Article 33(2) PCT).

- 6.1.1 The problem to be solved by the present invention may be regarded as:  
To facilitate the implantation procedure of an intervertebral cage to be filled with bone growth promoting material.
- 6.1.2 This problem is solved by the present invention, because the cage can be prefilled and closed before implantation, and the endplate can be positioned independently from this filling procedure.  
The solution to this problem proposed in claims 22 and 31 of the present application is neither disclosed nor fairly suggested by any of the documents cited in the international search report.  
The subject-matter of claims 22 and 31 does therefore involve an inventive step (Art. 33(3) PCT).
- 6.1.3 Claim 23 is dependent on claim 22 and as such also meets the requirements of the PCT with respect to novelty and inventive step.

**Re Item VII.**

The independent claims are not written in the two part form (Rule 6.3(b) PCT), which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

The features of the claims are not provided with reference signs placed in parentheses to increase the intelligibility of the claims (Rule 6.2(b) PCT). This applies to both the preamble and characterising portion (see the PCT Guidelines, III-4.11).

The documents D1 and D2 are not identified in the description and the relevant background art disclosed therein is not discussed (Rule 5.1(a)(ii) PCT).

**Re Item VIII.**

Claims 1 and 20 lack clarity in the sense of Art. 6 PCT:

The formation is tried to be defined by a reference to an end plate ("to mate with") and by reference to the intended positioning with respect to said end plate ("flush").

This represents a definition by a second entity and by the use of the end cap, and is therefore not clear (Guidelines C-III, 4.8a).



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## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/GB2005/000165

International filing date (day/month/year)  
21.01.2005

Priority date (day/month/year)  
22.01.2004

International Patent Classification (IPC) or both national classification and IPC  
A61F2/44, A61F2/30

Applicant  
DEPUY INTERNATIONAL LIMITED

### 1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Authorized Officer

Buchmann, G

Telephone No. +49 89 2399-2288



**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2005/000165

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2005/000165

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 26-30

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 26-30
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
  - the written form ☐ has not been furnished
  - ☐ does not comply with the standard
  - the computer readable form ☐ has not been furnished
  - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2005/000165

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

|                               |             |                 |
|-------------------------------|-------------|-----------------|
| Novelty (N)                   | Yes: Claims | 4,5,22,23,31    |
|                               | No: Claims  | 1-3,6-21,24,25, |
| Inventive step (IS)           | Yes: Claims | 22,23,31        |
|                               | No: Claims  | 1-21,24,25,     |
| Industrial applicability (IA) | Yes: Claims | 1-25,31         |
|                               | No: Claims  |                 |

**2. Citations and explanations**

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item III.**

Claims 26-30 of the present application define methods for use in an intervertebral fusion surgical procedure, comprising the step of introducing a cage into the intervertebral space. This step represents a method for surgical treatment of the human body in the sense of Rule 67.1 (iv) PCT. Therefore, no examination is carried out for these claims according to Art. 34 (4)(a)(i) PCT.

**Re Item V.**

- 1 Reference is made to the following documents:  
D1 : WO 00/45751 A (SYNTHES AG CHUR; SYNTHES ; MESSERLI, DOMINIQUE,  
D; PAUL, DAVID, C) 10 August 2000 (2000-08-10)  
D2 : EP 0 966 930 A (BIOMET MERCK LIMITED) 29 December 1999 (1999-12-29)

**2 INDEPENDENT CLAIM 1**

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.  
Document D1 discloses (see page 5 and 6, and fig. 1):  
An end cap (10) for an intervertebral cage (22), comprising
  - an annular body (12, 14),
  - a projection (12, 16), engaging with an edge of the cage, and
  - a formation 34, 36) which is suitable for mating with an end plate.

The definition in the present claim 1, that the outer surface of the body is flush with the surface of the end plate, is not a feature of the end cap itself (see below, clarity).

The subject-matter of claim 1 is therefore already known from document D1.

**3 INDEPENDENT CLAIM 13**

3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 13 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (see page 8, paragraph 4, and fig. 8):

An end cap (610) for an intervertebral cage (22), comprising

- an annular body (14),
- a projection (16), engaging with an edge of the cage, and
- flexible members (40) extending from the underside of the body, each flexible member having a grip for engaging with an inner surface of the cage.

The subject-matter of claim 13 is therefore already known from document D1.

**4 INDEPENDENT CLAIM 24**

4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 24 is not new in the sense of Article 33(2) PCT.

Document D2 discloses (see paragraphs (0037)-(0039)):

A method for use in an intervertebral fusion surgical procedure, comprising the steps of

- push fitting a first annular end cap into the end of a cage,
- packing the interior of the cage with a bone fusion enhancing material via an opening of the end cap.

The subject-matter of claim 24 is therefore already known from document D3.

**5 DEPENDENT CLAIMS 2-12, 14-21, 25**

Dependent claims 2-12, 14-21, 25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

See the documents cited in the international search report and the corresponding passages.

**6 INDEPENDENT CLAIMS 22 AND 31**

- 6.1 Document D1, which is considered to represent the most relevant state of the art, discloses (the references in parentheses applying to this document):

A kit for assembling into an intervertebral fusion device, comprising:

- An end cap (610) for an intervertebral cage (22), comprising
  - an annular body (14),
  - a projection (16), engaging with an edge of the cage, and
  - flexible members (40) extending from the underside of the body, each flexible member having a grip for engaging with an inner surface of the cage.

From this, the subject-matter of independent claims 22 and 31 differs in that:  
An end plate is provided having a formation mating with a formation on the end cap, such when assembled, the surfaces of the end cap and the end plate are flush.

The subject-matter of claims 22 and 31 is therefore novel (Article 33(2) PCT).

- 6.1.1 The problem to be solved by the present invention may be regarded as:  
To facilitate the implantation procedure of an intervertebral cage to be filled with bone growth promoting material.
- 6.1.2 This problem is solved by the present invention, because the cage can be prefilled and closed before implantation, and the endplate can be positioned independently from this filling procedure.  
The solution to this problem proposed in claims 22 and 31 of the present application is neither disclosed nor fairly suggested by any of the documents cited in the international search report.  
The subject-matter of claims 22 and 31 does therefore involve an inventive step (Art. 33(3) PCT).
- 6.1.3 Claim 23 is dependent on claim 22 and as such also meets the requirements of the PCT with respect to novelty and inventive step.

**Re Item VII.**

The independent claims are not written in the two part form (Rule 6.3(b) PCT), which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

The features of the claims are not provided with reference signs placed in parentheses to increase the intelligibility of the claims (Rule 6.2(b) PCT). This applies to both the preamble and characterising portion (see the PCT Guidelines, III-4.11).

The documents D1 and D2 are not identified in the description and the relevant background art disclosed therein is not discussed (Rule 5.1(a)(ii) PCT).

**Re Item VIII.**

Claims 1 and 20 lack clarity in the sense of Art. 6 PCT:

The formation is tried to be defined by a reference to an end plate ("to mate with") and by reference to the intended positioning with respect to said end plate ("flush"). This represents a definition by a second entity and by the use of the end cap, and is therefore not clear (Guidelines C-III, 4.8a).